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10/615,383	07/09/2003	Timothy J. Foster	P06335US03/BAS	5842

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EXAMINER	
ARCHIE, NINA	
ART UNIT	PAPER NUMBER
1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,383	FOSTER ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/4/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5, 7-10, and 13-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5, 7-10, and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed 3-4-09. Claims 10 and 14 have been amended. Claims 1, 6, 11-12 have been cancelled. Claims 2-5, 7-10, and 13-19 are pending and under examination.

Objections/Rejections Withdrawn

2. In view of the Applicant's amendment and remark following objections/rejections are withdrawn.

a) The Objection to claim 6 because of the following informality, whereby the claim states "wherein" twice is withdrawn in light of cancellation of the claim.

b) The rejection of claim 6, under 35 U.S.C. 112, second paragraph, whereby the claim was confusing because the claim recites indefinite article "The" attempting to limit the isolated antibody as dependent claim, is withdrawn in light of cancellation of the claim.

c) The rejection of claims 8, 10 and 14-15, under 35 U.S.C. 112, second paragraph whereby, the claims did not recite an article such as "the" which encompass any isolated antibody/antisera, but then attempt to limit the isolated antibody/antisera, is withdrawn in light of applicant's amendment thereto.

d) Rejection to claim 6 under 35 U.S.C. 102(b) as being anticipated by Guss et al WO1997/48727 is withdrawn in light of cancellation of the claim.

e) Rejection to claim 6 under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al US Patent No. 6,380,370 Date April 30, 2002 (US Filing Date August 13, 1998) is withdrawn in light of cancellation of the claim.

New Grounds of Objections

Claim Objections

3. Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 is drawn to an isolated antibody according to claim 7,

which is raised against the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis*, and does not further limit the isolated antibody in claim 7. Therefore, claim 4 as depending from claim 7, is broadening. The claims should indicate that the claims are further limiting the subject matter. Appropriate correction is required.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2-5, 7-10, and 13-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated antibody that binds to an SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis wherein the SdrG fibrinogen-binding protein is encoded by the nucleic acid comprising nucleic acids 102- 2894 of SEQ ID NO:7 (claim 7), wherein the protein is cell-wall associated, and binds both soluble and immobilized fibrinogen (claim 2), wherein the antibody recognizes a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16) (claim 3), which is raised against the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 4), which is raised against the A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 5), wherein the isolated antibody recognizes the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 8), a diagnostic kit comprising the antibody and a means for identifying binding by said antibody (claim 9), the isolatedlsolated antisera containing the antibody (claim 10), wherein said antibody is reactive with a protein that is cell wall-associated,

exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated from coagulase-negative Staphylococcus epidermidis (claim 13), wherein the protein comprises the SdrG fibrinogen-binding protein isolated from coagulase-negative Staphylococcus epidermidis (claim 14), wherein the antibody binds to the ligand binding A region of the SdrG fibrinogen-binding protein isolated from coagulase-negative Staphylococcus epidermidis (claim 15), a diagnostic kit comprising the antibody and a means for identifying binding by said antibody (claim 16), a diagnostic kit comprising the antibody and a means for identifying binding by said antibody (claim 17), an isolated antibody that binds to the ligand binding A region of an SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis wherein said region is encoded by the nucleic acid having the sequence of nucleotides 252 to 1895 of SEQ ID NO:7 (claim 18), wherein the ligand binding A region of an SdrG fibrinogen-binding protein has the sequence of from amino acid 51 to amino acid 598 of SEQ ID NO:10 (claim 19).

The specification discloses SEQ ID NO: 7 and SEQ ID NO: 10 that encodes for the Staphylococcus epidermidis SdrG fibrinogen-binding protein (a polypeptide with defined structure and function). Consequently, SEQ ID NO:7 and SEQ ID NO:10 meet the written description provision of 35 USC 112,first paragraph. However, the rejected claims (2-5, 7-10, and 13-17) are directed to an isolated antibody which binds to an SdrG fibrinogen-binding protein which encompasses sequences that selectively bind to nucleotides 102-2894 of SEQ ID NO: 7. Furthermore the aforementioned claims (18-19) are directed to an isolated antibody binds to the ligand binding A region of an SdrG fibrinogen-binding protein which encompasses sequences that selectively binds to nucleotides 252-1895 of SEQ ID NO: 7, wherein the ligand binding A region of an SdrG fibrinogen-binding protein has the sequence of from amino acid 51 to amino acid 598 of SEQ ID NO:10 (claim 19).

The specification proposes that the skilled artisan would be capable of an isolated antibody binding to a known nucleic acid sequence encoding a known protein sequence disclosed as SEQ ID NO: 7 (2-5, 7-10, and 13-17) and further SEQ ID NO: 10 (claims 18-19). However SEQ ID NO: 7 and SEQ ID NO: 10 have specific biological properties dictated by the structure of the protein and the corresponding structure of the structural nucleotide sequence

which encodes it. There must be a nexus between the structure of a nucleotide sequence and the structure of the protein encoded, and the function of that encoded protein.

The specification has not shown that an antibody binds to SdrG fibrinogen-binding protein encoded by nucleotides from 102-2894 of SEQ ID NO: 7, nucleotides 252-1895 of SEQ ID NO: 7, and amino acids from 51-598 of SEQ ID NO:10 as claimed. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotides encoding a representative number fibrinogen binding protein that binds to an isolated antibody, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed.

With the exception of an isolated polypeptide comprising SEQ ID NO:7 and SEQ ID NO: 10, the skilled artisan cannot envision all the contemplated variants and binding fragments because the genus is so highly variant and therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

Consequently, the instant claim encompasses corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity. homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.
Vas-Cath Inc. v. Mahuxkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is" now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO. 7 and further SEQ ID NO: 10 aformentioned above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required.

See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.~ 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found uanpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.
Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that:
...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10USPQ2d 1614, 1618 (Fed. Cir. 1989) C [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, stmctu3:es, figu3:es, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2dat1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by stmctu3:e, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiersv. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itsel£." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itsel£. No

sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 7 and further SEQ ID NO: 10, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3, 5, 8-9, 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 3 is rendered vague and indefinite by the use of the term "recognizes" since it is not explicitly defined in the specification. "Recognizes" has no art defined meaning with respect to a antibody. Therefore, the skilled artisan would not be readily apprised of the metes and bounds of "recognizes" nor how to assess such. It is unclear how to interpret what is considered "recognizes" and inasmuch as it is not a recognized term and not defined in the specification.

As to claims 5, 8, 15, and 18 is rendered vague and indefinite by the use of the term "A region" since it is not explicitly defined in the specification. It is unclear under what constitutes "A region" of the SdrG fibrinogen-binding protein. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

As to claims 9 and 16-17, states " a diagnostic kit comprising the antibody and a means for identifying binding by said antibody" that invokes 35 U.S.C. 112 6th paragraph. However the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material or acts perform the claimed function.

Applicant is required to: (a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or (b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or (c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP 2181 and 608.01(o).

Claim 18 recites the limitation "region" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 2-5, 7-10, and 13-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Doucette-Stamm et al. US Patent No. 6,380,370 Date August 13, 1998.

Claims 2-5, 7-10, and 13-19 are drawn to an isolated antibody that binds to an SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis*, wherein the SdrG

fibrinogen-binding protein is encoded by the nucleic acid comprising nucleic acids 102-2894 of SEQ ID NO:7 (claim 7), wherein the protein is cell-wall associated, and binds both soluble and immobilized fibrinogen (claim 2), wherein the antibody recognizes a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16) (claim 3), which is raised against the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 4), which is raised against the A region of the SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis (claim 5), wherein the antibody recognizes the ligand binding A region of the SdrG fibrinogen-binding protein from coagulase-negative *Staphylococcus epidermidis* (claim 8); a diagnostic kit comprising the antibody and a means for identifying binding by said antibody (claim 9), the isolated antisera containing the antibody (claim 10), wherein said antibody is reactive with a protein that is cell wall-associated, exhibits cation-dependent ligand-binding and has a highly conserved motif of which the consensus sequence is TYTFTDYVD (SEQ ID NO: 16), wherein the protein is isolated from coagulase-negative *Staphylococcus epidermidis* (claim 13); an antibody wherein the protein comprises the SdrG fibrinogen-binding protein isolated from coagulase-negative Staphylococcus epidermidis (claim 14); an isolated antibody, wherein the antibody binds to the ligand binding A region of the SdrG fibrinogen-binding protein isolated from coagulase-negative Staphylococcus epidermidis (claim 15); a diagnostic kit comprising the antibody and a means for identifying binding by said antibody (claim 16); a diagnostic kit comprising the antibody according to Claim 3 and a means for identifying binding by said antibody (claim 17); an isolated antibody that binds to the ligand binding A region of an SdrG fibrinogen-binding protein from coagulase-negative Staphylococcus epidermidis wherein said region is encoded by the nucleic acid having the sequence of nucleotides 252 to 1895 of SEQ ID NO:7 (claim 18), wherein the ligand binding A region of an SdrG fibrinogen-binding protein has the sequence of from amino acid 51 to amino acid 598 of SEQ ID NO:10 (claim 19).

Doucette-Stamm et al. disclose a *Staphylococcus epidermidis* fibrinogen protein amino acid identical to amino acids 102-2894 of SEQ ID NO:7 (see STIC results attached), a *Staphylococcus epidermidis* fibrinogen protein amino acid identical to amino acids 252 to 1895

of SEQ ID NO:7 (see STIC results attached), a *Staphylococcus epidermidis* SdrG fibrinogen protein amino acid identical to amino acids 51-598 of SEQ ID NO:10 (see STIC results attached), and a *Staphylococcus epidermidis* fibrinogen protein consensus sequence amino acid identical to amino acids TYTFTDYVD SEQ ID NO: 16. Moreover, Doucette-Stamm et al. et al. disclose that said protein was used to raise antibodies (see abstract, column 9, column 22 lines 25-40), column 25 lines 10-20, column 27 lines 10-17, column 41 lines 1-55). Consequently, Doucette-Stamm et al. anticipates all the limitations of the instant claims.

Conclusion

7. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nina A Archie
Examiner
GAU 1645
REM 3B31

/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645